HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance
D1278B

4298 Elysian Fields Avenue
New Orleans, LA 70122

March 21, 1997

WARNING LETTER NO. 97-NOL-34

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Nordan, President
Nordan Smith Welding Supplies
5051 Highway 42
Hattiesburg, Mississippi 39403

Dear Mr. Nordan:

During an inspection of your manufacturing facility, located at 317 W. Rankin Street, Jackson, Mississippi, conducted on February 24, 25, 28. 1997, our investigator documented deviations from the Current Good Manufacturing Practice regulations. These deviations cause your drug products, liquid Oxygen, USP and compressed Oxygen, USP, to be adulterated within the meaning of Section 502(a)(2)(B), in that the controls used for the manufacture, processing, packing, or holding of this product are not in conformance with Current Good Manufacturing Practice regulations (Title 21, Code of Federal Regulations, Part 210 and 211).

Our inspection revealed the following CGMP deviations:

1. Failure to establish scientifically sound and appropriate test procedures for the assay of Oxygen, USP, in that you have no written procedure for the operation and/or maintenance of the [redacted] Oxygen Analyzer used to assay the finished product.

2. Failure to review and approve, prior to product distribution, the Packaging Control Records which document the manufacture and testing of compressed Oxygen, USP and liquid Oxygen, USP.

3. Failure to date the Packaging Control Records with the date actually reviewed, in that the records were reviewed at a later date and dated as being reviewed on the date manufactured.

4. Failure to have a responsible individual's approval of the written procedures for the manufacture of compressed Oxygen,USP and liquid Oxygen, USP.

5. Failure to have a current master label for liquid Oxygen, USP in the procedure manual.

6. Failure to identify storage areas for oxygen cylinders.

7. Failure to include on all labels the net quantity of contents and/or the required Federal caution prescription statement.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana,

70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mrs. Hardin.

Sincerely,

James E. Gamet
District Director
New Orleans District

cc: Mr. Bobby Brown
Corporate Sales Manager
Nordan Smith Welding Supplies
5051 Highway 42
Hattiesburg, Mississippi 39403

Mr. Paul R. Lee
Store Manager
Nordan Smith Welding Supplies
317 W. Rankin Street
Jackson, Mississippi 39207

Enclosure: FDA-483

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